

(a) Problems identified during the evaluation of calibration and control data for each test method;

(b) Problems identified during the evaluation of patient test values for the purpose of verifying the reference range of a test method; and

(c) Errors detected in reported results.

§493.1707 Standard; Proficiency testing assessment.

Under subpart H of this part, Proficiency Testing, the corrective actions taken for any unacceptable, unsatisfactory, or unsuccessful proficiency testing result(s) must be evaluated for effectiveness.

§493.1709 Standard; Comparison of test results.

(a) If a laboratory performs the same test using different methodologies or instruments, or performs the same test at multiple testing sites, the laboratory must have a system that twice a year evaluates and defines the relationship between test results using the different methodologies, instruments, or testing sites.

(b) If a laboratory performs tests that are not included under subpart I of this part, Proficiency Testing Programs, the laboratory must have a system for verifying the accuracy of its test results at least twice a year.

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§493.1711 Standard; Relationship of patient information to patient test results.

For internal quality assurance, the laboratory must have a mechanism to identify and evaluate patient test results that appear inconsistent with relevant criteria such as—

- (a) Patient age;
- (b) Sex;
- (c) Diagnosis or pertinent clinical data, when provided;
- (d) Distribution of patient test results when available; and
- (e) Relationship with other test parameters, when available within the laboratory.

§493.1713 Standard; Personnel assessment.

The laboratory must have an ongoing mechanism to evaluate the effectiveness of its policies and procedures for assuring employee competence and, if applicable, consultant competence.

§493.1715 Standard; Communications.

The laboratory must have a system in place to document problems that occur as a result of breakdowns in communication between the laboratory and the authorized individual who orders or receives the results of test procedures or examinations. Corrective actions must be taken, as necessary, to resolve the problems and minimize communication breakdowns.

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§493.1717 Standard; Complaint investigations.

The laboratory must have a system in place to assure that all complaints and problems reported to the laboratory are documented. Investigations of complaints must be made, when appropriate, and, as necessary, corrective actions are instituted.

§493.1719 Standard; Quality assurance review with staff.

The laboratory must have a mechanism for documenting and assessing problems identified during quality assurance reviews and discussing them with the staff. The laboratory must take corrective actions that are necessary to prevent recurrences.

§493.1721 Standard; Quality assurance records.

The laboratory must maintain documentation of all quality assurance activities including problems identified and corrective actions taken. All quality assurance records must be available to HHS and maintained for a period of 2 years.

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Subpart Q—Inspection

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